



# CERTIFICATE OF ANALYSIS

**DRAXIMAGE MAA MACROSALB (10 vials/kit)**  
2.5 mg of Stannous Albumin Macro Aggregate / vial

<b># Certificate:</b>	2021JA25-1		
<b>Batch Number:</b>	0M383	<b>Manufacturing Date:</b>	2020NO24
<b>Lot Number (FP):</b>	0M383A	<b>Expiry Date:</b>	11/2022
<b>Product Number:</b>	30000001020	<b>Specification Number and Version:</b>	30000001020_v01
<b>Standard of Testing:</b>	House, USP <sup>1</sup>	<b>Date of Release: (Date with QA Initials)</b>	MMN 2021 FE 11

## Tests on the Lyophilized product

<u>Test Description</u>	<u>Analytical Method</u>	<u>Specifications</u>	<u>Results</u>
Description	10019	A white freeze-dried plug or powder, clean and free of foreign matter. The flip-off cap is blue.	Conforms
Resuspendability	10079	A white suspension which may separate on standing.	Conforms
pH	10005	5.2 – 6.0	5.4
Loss on Drying	10021	≤ 5%	<1%
Particle Density	10088	3 - 8 x 10 <sup>6</sup> aggregated albumin particles in each vial	3 x 10E6 part./vial
Particle Size	10080	Particle Size < 10 µm: ≤ 10%	6%
		Particle Size ≥ 10 µm - ≤ 70 µm: ≥ 90%	94%
		Particle Size > 100 µm: ≤ 0.2%	< 0.1%
		Particle Size > 150 µm: none	None
MAA Identification	10000	A blue color develops.	Conforms
SnCl <sub>2</sub> .2H <sub>2</sub> O Assay	10039	≥ 0.06 mg/vial	0.10 mg/vial
Total Tin Assay	10040	≤ 0.12 mg	0.10 mg/vial
Stannous Albumin Macro Aggregated Complex	10082	2.2 – 3.0 mg/vial	2.7 mg/vial
Human Serum Albumin	10068	3.5 – 6.5 mg/vial (or alternative method 10089)	5.1 mg/vial
Sodium Chloride	10084	0.96 – 1.44 mg/vial	1.34 mg/vial
Residual Solvents <sup>1</sup>	USP<467>	Meets USP requirements (No test required)	Conforms
Sterility <sup>1,2</sup>	10007	Sterile	Conforms
Bacterial Endotoxins	10008	≤ 16.5 EU/vial	< 1.0 EU/vial

<sup>2</sup> Outside testing

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MT 2021 JA26



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## Tests on the Reconstituted product

Test Description	Analytical Method	Specifications	Results
Radiochemical Purity	10043	Not less than 90% of the total radioactivity is found as aggregated albumin at the point of application, at 15 – 30 minutes post labeling.	100%
		Not less than 90% of the total radioactivity is found as aggregated albumin at the point of application, at least 12 hours post labeling.	100%
Centrifugation Procedure	10087	Not more than 10% of the total radioactivity is found in the supernatant liquid, at 15 – 30 minutes post labeling.	4%
		Not more than 10% of the total radioactivity is found in the supernatant liquid, at least 12 hours post labeling.	4%
Biological Distribution	10044	In not less than 2 of 3 animals, at 15 – 30 minutes post labeling, not less than 80% of the radioactivity is found in the lungs of the animal at 15 minutes post injection.	1: 93% 2: 92% 3: 98%
		In not less than 2 of 3 animals, at 15 – 30 minutes post labeling, not more than a total of 5% of the radioactivity is found in the liver of the animal at 15 minutes post injection.	1: 1% 2: 1% 3: 1%
		In not less than 2 of 3 animals, at 15 – 30 minutes post labeling, not more than 5% of the radioactivity is found in the kidneys of the animal at 15 minutes post injection.	1: 1% 2: 1% 3: 1%
		In not less than 2 of 3 animals, at 12 -24 hours post labeling, not less than 80% of the radioactivity is found in the lungs of the animal at 15 minutes post injection.	1: 89% 2: 94% 3: 90%
		In not less than 2 of 3 animals, at 12 - 24 hours post labeling, not more than a total of 5% of the radioactivity is found in the liver of the animal at 15 minutes post injection.	1: 2% 2: 2% 3: 2%
		In not less than 2 of 3 animals, at 12 – 24 hours post labeling, not more than 5% of the radioactivity is found in the kidneys of the animal at 15 minutes post injection.	1: 1% 2: 2% 3: 1%

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Standard of Testing:	House, USP <sup>1</sup>		

This batch of product has been tested by Jubilant DraxImage Quality Control Laboratory under Canadian Establishment License Number **101869-A** and complies with the specification requirements.

MUSTAPHA TOLLABI  
QC Sr. Supervisor

M. Tollabi

2021JA26

Verified by:  
Name and Title

Signature

Date

FAIZA MINOVI QA Associate

F. Mino

2021 FE 11

Approved by:  
Name and Title

Signature

Date

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